



June 16, 2004

Dockets Management Branch (HFA-305)  
Docket No. 2003N-0076  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

**Re: Food Labeling: Trans Fatty Acids in Nutrition Labeling; Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements: Reopening of the Comment Period, Docket No. 2003N-0076**

To Whom It May Concern:

On behalf of the National Cattlemen's Beef Association (NCBA), we would like to thank the Food and Drug Administration for the opportunity to provide comment on the nutrition labeling of *trans* fat in light of the recent 2003 Institute of Medicine, National Academy of Science (IOM/NAS) report, *Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification*. Producer-directed and consumer-focused, the National Cattlemen's Beef Association is the trade association of America's cattle farmers and ranchers, and the marketing organization for the largest segment of the nation's food and fiber industry.

FDA has requested comment on several aspects related to nutrition labeling of *trans* fat during this reopening of the comment period. NCBA is pleased to add our comments below on these issues.

**Approach recommended in the 2003 IOM/NAS report to estimate minimum *trans* fatty acid intakes within a nutritionally adequate North American Diet and use of this value to establish a DV for *trans* fat.**

To establish a Daily Value (DV) for *trans* fat, the IOM/NAS report suggests using food composition data, menu modeling, and data from dietary surveys to estimate minimum intakes consistent with nutritionally adequate and health-promoting diets for diverse populations. Specifically, the report suggests estimating minimal *trans* fat intake levels via menu modeling and then further evaluating them against achievable health-promoting diets (identified in dietary survey data) in order to arrive at appropriate recommendations for the intake of *trans* fat.

While NCBA agrees with this approach, the availability of such data over a wide range of diets and among diverse populations is sorely lacking at this time. To apply data from the limited datasets that are available is premature. More research is necessary to help determine realistic levels of *trans* fat and saturated fat in the context of nutritionally adequate and realistic diets that cover diverse populations, in order for label information to be applicable and meaningful. Further, it might also be helpful if such research determined the intakes of "naturally" occurring vs. "man-made" TFA, in these nutritionally adequate and realistic diets.

**Development of a joint DV for saturated and *trans* fats. As well as the use of the same approach that the 2003 report recommended for establishing a DV for *trans* fats to establish a new DV for saturated fat that would then be added to the DV for *trans* fats to establish a new combined DV, or, alternatively, to establish a joint DV for saturated and *trans* fats - in the case that joint DV for saturated and *trans* fat is pursued.**

NCBA cannot support recommendations for a joint or combined DV unless other naturally occurring *trans* fats are exempted from labeling. The impetus behind development of a joint or combined DV for saturated and *trans* fats is because of their propensity to raise blood cholesterol levels. However, naturally occurring *trans* fats, such as those found in beef and dairy foods, are not harmful and in fact, may be beneficial to health. For this reason, naturally occurring *trans* fats should be exempted from labeling. In Denmark, the Danish Veterinary and Food

Administration has recognized the critical distinction between man-made and naturally occurring *trans* fats and its Orders specifically exempt naturally occurring *trans* fatty acids in animal fats or products from labeling (1).

There is enormous potential for confusion if information about *trans* fatty acids is oversimplified and consumers assume that all *trans* fatty acids act in the same way. In terms of both structure and function, the differences between man-made and naturally occurring *trans* fatty acids result in very different health effects (2). Animal products are nutrient dense and are not a source of harmful *trans* fatty acids. The natural *trans* fat component of the total fat that beef and dairy provide is an intrinsic component of the food and cannot be engineered out as is the case with snack foods and margarines. The data support caution in consuming elaidic acid and other *trans* fatty acids generated by hydrogenation of vegetable oils in snack foods and margarines, but a comparable quantity and quality of scientific data does not exist to indict naturally occurring *trans* fatty acids, such as vaccenic acid

FDA has recognized this to some degree by exempting conjugated linoleic acid (CLA) from the Nutrition Facts panel because of its health benefits. However, other naturally occurring *trans* fatty acids, including vaccenic acid (VA; 18:1, *trans*-11), may also have health promoting effects. A significant portion of vaccenic acid is converted to *cis*-9, *trans*-11 CLA via endogenous synthesis in humans and therefore must be considered when assessing CLA status (3). Several animal studies (4-7) and human studies (3,8,9) have investigated this precursor role, as well as its potential to directly exert anticarcinogenic properties.

For example, one study found that increasing amounts of pure VA resulted in a progressive rise in the tissue concentrations of CLA and a corresponding decrease in the number of premalignant mammary lesions (5). Another study using diets varying in VA and *cis*-9, *trans*-11 CLA content found that the conversion of dietary VA to CLA resulted in a dose dependent increase in the accumulation of CLA in mammary fat and that this was accompanied by a corresponding decrease in both tumor incidence and number (4). Studies in humans also demonstrate that vaccenic acid intake can increase bioavailable CLA (3,8,9). While direct feeding trials comparing natural to man-made *trans* fats have not yet been conducted, the epidemiological evidence indicates that animal derived *trans* fats appear to exert a beneficial effect. Data from the Nurses Health Study reveal that *trans* fatty acids derived from vegetable fats increase risk of coronary heart disease, while *trans* fatty acids of animal origin decrease the risk (10). Other epidemiological data support this finding (11,12). Hodgson and colleagues also found that while intake of elaidic acid and *trans*-10 octadecaenoic acid were positively correlated with coronary heart disease, intake of other *trans* fatty acids, including vaccenic acid (found in ruminant animal fats), was not (13).

In summary, the data support caution in consuming elaidic acid and other *trans* fatty acids generated by hydrogenation of vegetable oils but a comparable quantity and quality of scientific data does not exist to indict naturally occurring *trans* fatty acids. While we recognize that the weight of evidence of *trans* fat effects are being levied based on the effects associated with blood cholesterol, we believe that the harmless effects, as well, as the other potential health benefits that some naturally occurring *trans* fats, such as vaccenic acid, provide should also be recognized and therefore, exempted from nutrition labeling requirements.

**How might either a DV for *trans* fat or a joint DV for saturated and *trans* fat affect the qualifying criteria for *trans* fat in *trans* fat nutrient content claims and qualifying criteria for saturated and *trans* fat in current nutrient content claims for saturated fat and cholesterol, lean and extra lean claim, and health claims that contain a message about cholesterol-raising lipids, as well as disclosure and disqualifying criteria for saturated and *trans* fats to help consumers make healthy food choices?**

Provided that naturally occurring *trans* fats are exempted from nutrition labeling, we believe the current qualifying criteria for claims, including those for lean and extra lean, are appropriate. NCBA encourages FDA during its evaluation process to determine a DV that is realistic and meaningful in accordance with American eating patterns. The IOM/NAS report itself provides as a guiding principle that “The DVs for saturated fats, *trans* fatty acids, and cholesterol should be set at a level that is as low as possible in keeping with an *achievable* health-promoting diet” (14). Very low levels of percentage of saturated fat in the diet are not realistic for the majority of the population, and will be even more difficult to attain in combination with *trans* fats. For example, while a diet of 3-5% of calories from saturated fat may be possible under very carefully controlled situations, such diets offer limited variety and palatability and are unattainable for the general population. The attempt to achieve an extremely low level of calories from saturated and *trans* fat (at 3-5% and even 7%, as with

the Step II diet) would require significant changes in dietary patterns for many consumers and population groups and may result in unknown and unquantifiable health risks. Also, such diets are less likely to offer variety and palatability while also encouraging compliance. Unless naturally occurring *trans* fats are exempted, this could result in less than optimal intakes of particular vitamins and minerals for many people - for example if nutrient-rich foods like lean beef are unwittingly omitted from the diet. There is a critical need for more research to help define a realistic %DV for saturated fat and *trans* fat acids in realistic diets for the general population. Until this further research is completed, NCBA would urge that the current %DV of 10% be retained.

Beef is the number one source of protein, zinc and vitamin B12 in American diets, the number two food source of vitamin B6, and the number three food source of iron (behind fortified cereal and yeast bread) and niacin. Its bundle of nutrients is beneficial for growing, developing and maintaining overall health through all of life's stages, from childhood to senior years. Multiple studies demonstrate the importance of nutrients such as iron (15-19), zinc (20-25), and B vitamins (26-28), all of which are naturally found in beef. Unfortunately, unless naturally occurring *trans* fats are exempted from labeling, consumers will think that the *trans* fats in beef and dairy will negatively impact their health, and this is not the case. A recent assessment of nutrient composition of highly consumed snack foods for the USDA National Nutrient Database (29) revealed that the *trans* fatty acid content of these foods has decreased significantly since health concerns surfaced. Labeling of *trans* fatty acids in animal products will convey the wrong message to consumers leading them to believe that a *trans* fat-free cookie or chip is healthier than naturally nutrient rich foods, such as lean beef and lowfat dairy foods.

The beef industry has committed numerous resources to help improve the nutritional health of Americans and ensure beef can play a role in a healthy lifestyle. For example, we have responded to consumer demand and public health recommendations to help Americans decrease fat and saturated fat intake by providing leaner cuts of beef. Today, at least 19 cuts of beef meet government guidelines for lean – with less than 10 grams of total fat, 4.5 grams or less of saturated fat, and less than 95 milligrams of cholesterol per serving (and per 100 grams). In fact, 10 of these cuts have just one more gram or less of saturated fat than a skinless chicken breast, chicken's leanest cut. In 2003, an updated version of the United States Department of Agriculture Nutrient Database was released that included new analytical data for beef retail cuts, showing that many cuts of beef have considerably less fat than they did 14 years ago. In fact, according to recent FreshLook retail data, 68% of all muscle cuts sold at retail meet government guidelines for "lean" (30). Additionally, 17 of the top 20 most popular retail whole muscle cuts meet government guidelines for lean (31). These changes are substantial and reflect the beef industry's considerable efforts to meet consumer demand and expectations, as well as public health recommendations. Including natural *trans* fats on the Nutrition Facts label would be unfair and misleading to consumers, since the natural *trans* fats found in beef do not affect blood cholesterol levels in the same way that man-made *trans* fats do.

**Would a DV for *trans* fat or joint DV for saturated and *trans* fat eliminate the necessity for considering a disclosure statement, in conjunction with nutrient content or health claims, concerning levels of saturated fat, *trans* fat, or cholesterol in a food or in the diet or a message about the role of such cholesterol raising lipids in increasing the risk of CHD? In addition, would such DVs eliminate the need for a footnote about *trans* fat, either alone or in combination with saturated fat and cholesterol?**

As indicated in our previous comments (dated December 16, 2002), we strongly discourage the use of footnotes and likewise, do not believe disclosure statements are necessary if a DV is provided.

The Nutrition Facts panel is not the place to educate consumers about the nuances of types of *trans* fat or saturated fat, or the potential health benefits, pro and con. Rather, the label should simply present the data stating the amount of a nutrient contained in a product. The particulars of explaining the aspects of amounts needed or the desire to consume more or less of nutrients is best left to the Dietary Guidelines or Food Guide Pyramid.

The IOM/NAS report acknowledges the lack of data on consumer use of nutrition labeling and recommends that regulatory agencies conduct a review of nutrition labeling, as well as significant consumer-based research on the understanding and use of nutrition labeling. To that end, it has identified 14 questions that could frame development of consumer research on nutrition labeling, which we strongly support.

Without information on consumer use and understanding of nutrition labels, there is no way to judge their effectiveness on improving the diets and health of Americans, which was the reason they were developed in the

first place. Given the recent recommendations of the FDA's Obesity Working Group, it may be more effective from an educational and utilization perspective to take a broader look at nutrition labeling and revise the entire Nutrition Facts panel at one time, as opposed to implementing numerous specific changes individually in the years to come.

NCBA appreciates the opportunity to comment on these important issues. Due to the fact that naturally occurring *trans* fats provide beneficial health effects, we urge you to exempt them from nutrition labeling requirements. Failing to do so will mislead consumers because they will have no way of knowing that the *trans* fats found in lean beef act very differently than man-made *trans* fats and may unintentionally influence consumers to eliminate naturally nutrient rich foods like beef from their diets.

Thank you for your consideration.



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